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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,717	09/24/2001	Barton F. Haynes	1579-599	4196

7590 10/11/2002

NIXON & VANDERHYE P.C.  
8th Floor  
1100 North Glebe Road  
Arlington, VA 22201

EXAMINER

STUCKER, JEFFREY J

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 9/5/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-27 is/are pending in the application.
- Of the above claim(s) 1-15 & 18-27 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 16 & 17 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8411
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Other notice to comply w/ sequence rules

Office Action Summary

Applicant's election with traverse of Group II, in Paper No. 10 is acknowledged. The traversal is on the grounds that a complete search of the immunogen of Group II would necessitate a complete search of the subject matter of Group I and would not be an undue burden on the examiner. Applicant further asserts that there was no justification for restricting out the method of claim 19 set forth. This is not found persuasive because the search for an immunogen comprising HIV envelope bound to a ligand as in group I is not same as the immunogen of group I with the additional element of an HR-2 peptide. The search for an immunogen comprising HIV envelope, a ligand, and HR-2 is not going to be coextensive with a search of HIV envelope bound to a ligand and the additional limitations of various species of envelope proteins, ligands, etc. In addition, the method of claim 19 is distinct from the elected invention, not only because it is a method versus a composition, but because the composition can be used in materially different methods such as immunoassays or column chromatography and the method of producing neutralizing antibodies can be done with different antigens such as the V3 loop of HIV gp120.

The inclusion of claim 18 with this group is an inadvertent mistake; the claim should be included with group I as it is HIV envelope bound to a ligand without the requirement of HR-2 peptide as per claims 16 and 17. The examiner apologizes for any confusion

this may have caused. Therefore, claims 1-15 and 18-27 are withdrawn from consideration and claims 16 and 17 are pending and rejected.

The requirement is still deemed proper and is therefore made FINAL.

The disclosure is objected to because of the following informalities:

1) The continuing data in the original first paragraph of the specification was not canceled when the new continuing data paragraph was added by a preliminary amendment, and

2) the new continuing data paragraph that was added by preliminary amendment needs to be updated.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of

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37 C.F.R. §§ 1.821-1.825 for the reasons set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Failure to fully comply in response to this Office Action will be treated as a non-responsive reply.

A reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio  
(<http://www.uspto.gov/ebs/efs/downloads/documents.htm>),  
EFS Submission User Manual - ePAVE)

2. Mailed to:  
U.S. Patent and Trademark Office  
Box Sequence, P.O. Box 2327  
Arlington, VA 22202

3. Mailed by Federal Express, United Parcel Service or other delivery service to:

U. S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window, Box Sequence  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, Virginia 22202

4. Hand Carried directly to the Customer Window at:  
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Crystal Plaza Two, Lobby, Room 1B03, Box Sequence,  
Arlington, Virginia 22202

Claim 16 is objected to for being dependant upon a non-elected claim.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

There is no specific and substantial utility for the claimed immunogen comprising a complex of HIV envelope protein, ligand, and H2 peptide. There is no disclosure as to what type of immune response is expected from this "immunogen" and what usefulness that response may have. There are not even any teachings in the specification or the art of using this complex as an immunogen. Though it is interesting that H2 binds to H1 when envelope protein is bound to a ligand, this has no patentable utility. While the binding of envelope to a ligand exposes a cryptic epitope, with the detachment of H2 from H1 and the uncoiling of H1, adding H2 peptide covers H1 by binding to it, thereby shielding the cryptic epitope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rendered indefinite in that they only describe the composition by an arbitrary name. While the name itself may have some notion of activity of the protein, there is nothing in the claims which distinctly describes the protein. Claiming a biochemical molecule by a particular name given to the protein by the various workers in the field fails to distinctly claim what that protein is and what the composition is made of.

It is not clear what is meant by "upregulates". Does this mean that the binding region on the protein is exposed?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 17 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The instant invention is apparently free of the prior art of record as there are no teaching or suggestions of combining HIV envelope, ligand, and H2 peptide into a single complex.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 308-4426.

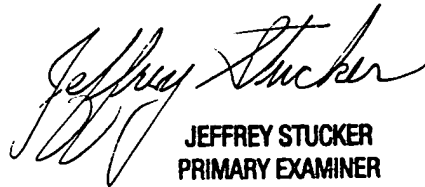
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
JEFFREY STUCKER  
PRIMARY EXAMINER

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING  
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7.

Other: \_\_\_\_\_

**Applicant must provide:**

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123

For CRF submission help, call (703) 308-4212

For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.